How Has Your Practice Changed With the Availability of Fenestrated Devices?

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Dr. Maldonado has disclosed that he is a consultant to Cook Medical and was part of the Cook fenestrated clinical trial.

The arrival of fenestrated technology for treating abdominal aortic aneurysms (AAAs) has been met with enthusiasm by many vascular surgeons and interventionists. Yet, even the most ardent champions of this new tool recognize that the majority of patients with abdominal aortic pathology remain good candidates for traditional stent grafts and will not require fenestration to achieve a suprarenal seal. My practice at a major metropolitan tertiary care center has allowed me to participate in many of the cutting-edge endovascular clinical trials for endovascular aneurysm repair (EVAR) and thoracic EVAR, including the Cook Fenestrated trial for AAA (Cook Medical, Bloomington, IN). I have come to appreciate that a significant number of my patients who would otherwise be treated with traditional stent grafts are better suited for fenestrated EVAR. In particular, I am more ready to commit to fenestrated EVAR (FEVAR) in those who had prohibitive risks for open surgery and in whom I may have accepted a 5- to 10-mm neck seal for lack of better alternatives.

Although the snorkel technique for preserving renal and visceral flow during EVAR has gained some traction at certain centers, I have largely abandoned this in favor of FEVAR. Unlike snorkel procedures, in most cases, FEVAR can be performed without the required brachial access and associated risks. In addition, I am more comfortable with a circumferential intact seal provided by a fenestrated device compared with the inevitable "gutters" created by the snorkel approach.

In addition, part of the learning curve required for FEVAR involves familiarity with three-dimensional imaging software (ie, TeraRecon, Inc., Foster City, CA). I have completely adopted this in my practice for all EVAR/thoracic EVAR cases and have found that it allows me to size and plan more accurately.

Finally, FEVAR has allowed me to make a case to my hospital administration by insisting on the importance of a hybrid operating room to perform these cases. This technology has served as a catalyst for my hospital to provide me with the matching imaging essential to perform such complex cases.

As with any new technology, long-term follow-up is critical and will ultimately help us better select which patients are suited for FEVAR. This new and exciting tool should serve as a platform for future-generation branched and fenestrated devices to treat the paravisceral and thoracic aorta.

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Dr. Sanchez discloses financial relationships including consulting and research for Cook Medical, Gore & Associates, Aptus Endosystems, Endologix, Inc., Lombard Medical, Inc., Medtronic, Inc., and TriVascular, Inc.

The awaited approval of fenestrated devices in the United States has increased the ability to treat high-risk operative patients who have complex aortoiliac anatomy with appropriate endovascular devices. Until recently, many patients with short and complex infrarenal aortic necks were not candidates for open surgical repair and have been treated with the currently available infrarenal devices, with or without additional mesenteric and renal stents or "homemade" fenestrated devices, with variable results. The currently approved fenestrated devices allow us to treat patients with a

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device that has been shown to have excellent short- and long-term results and is specifically designed to treat these patients.

The ability to customize the device to specific anatomy permits accommodation of the fenestrated device to the vast majority of patients with juxtarenal aneurysms who are being considered for treatment. The availability of these devices has significantly increased the number of patients with juxtarenal and suprarenal aneurysms being referred for evaluation and potential treatment. Additionally, the availability of fenestrated devices has increased the interest and commitment of endovascular companies to improve and develop new fenestrated and branched technologies for use in the United States. Currently, we are evaluating two "off-the-shelf" fenestrated devices that will avoid the need for device customization and construction delays of 4 to 6 weeks and will likely increase the number of patients who can be treated with fenestrated technologies.

We still have to keep in mind that these devices will allow us to treat patients with suitable anatomy for fenestrated endovascular repair. There are still major anatomical limitations to the application of these devices, including the need for suitable iliac artery access that allows in situ manipulation of the device; three or fewer aortic branches of appropriate size without severe calcification, stenoses, or previous stents; limited aortic angulation; and a healthy, nonaneurysmal aortic segment to seal the device long-term. Patients are very interested in the least invasive treatment modality available to exclude their aneurysm, but we have to continue to weigh the operative risk and the anatomical suitability when considering the use of these endovascular devices or well-established open surgical techniques. As we evaluate more patients for fenestrated devices, the number treated with open surgical techniques has also increased. Open surgical repair in suitable candidates should continue to be the treatment of choice.

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Dr. Woo has disclosed that he has received grants, honoraria, and consulting payment from Cook Medical, Medtronic, Endologix, and Atrium.

We have all been eagerly awaiting the availability of fenestrated devices in the United States for some time. Most recently, the Zenith fenestrated device (Cook Medical) has been approved for commercial use by the FDA, and the Ventana device (Endologix, Inc., Irvine, CA) has begun its pivotal trial. Medtronic, Inc. (Minneapolis, MN) will also soon be launching a clinical trial with their abdominal branched device. A significant component of my practice is composed of complex aortic work, and these devices have been a great benefit to the patients. Before the availability of these devices, I would perform open aortic surgery for most patients with pararenal and juxtarenal aneurysms. Although these patients would still do well from an overall standpoint, the perioperative recovery was much more difficult. Thus, the endovascular techniques have been terrific for these patients. Whereas with the evolution of standard EVAR, open infrarenal AAA repair became the "chip shot" open case, with the arrival of fenestrated devices, the pararenal open repair is now the "easy" operation. The patients who now undergo open repair typically have full type IV aneurysms and often have severe concomitant aortoiliac disease and have undergone previous aortic operations as well. With fenestrated devices, the number of open repairs will continue to decline, again bringing forth the question of fellowship training for this procedure.

The availability of fenestrated devices has also altered my standard EVAR practice somewhat. In situations in which patients have a challenging neck (eg, thrombus, calcification, trapezoidal, angulated, short), I will now move forward with a fenestrated device that allows for seal in the more healthy pararenal aortic segment. Given the availability of these devices, there is no reason to compromise seal in a difficult neck with standard EVAR when a more optimal seal can be achieved with a fenestrated device.

Overall, we are very excited that fenestrated devices have finally arrived in the United States, so that more patients can receive the benefits of EVAR.

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Because we have had access to fenestrated devices since 2005, the availability of FDA-approved fenestrated devices will not significantly change our current practice of managing these complex patients. What is of significant interest is a 7-year retrospective look at how our practice has changed since having access to these devices.

Initially, we utilized these devices to manage patients with isolated branched vessel issues that needed to be preserved, such as isolated renal arteries. As we gained experience, the number of fenestrations targeted for treatment steadily increased to the point where we currently routinely perform four-vessel fenestration through various investigational device exemptions. Our practice, however, did not attempt these more complicated repairs at the outset. More complicated repairs were undertaken once significant experience was achieved, which occurs some time after 30 implants. This approach, along with strict adherence to Instructions for Use criteria for the devices, results in low procedural risks and target vessel loss similar to that reported in the literature.

Our approach to patients with short infrarenal necks is fairly conservative. Experience has taught us that in patients with < 15 mm of good-quality, disease-free, parallel aortic walls, utilizing fenestrated grafts appears to confirm a longer reintervention-free period compared to placing infrarenal devices for repair outside the intended Instructions for Use. However, it is essential when implanting these newer devices that a minimum good-quality neck length of 20 to 25 mm be targeted. The proximal implantation region must not be funnel-shaped or show signs of early dilatation (ie, the diameter is larger than the more proximal visceral section). It is only in this fashion that we can minimize the need for secondary interventions with fenestrated grafts that will be significantly more difficult to repair with endovascular techniques if they fail. ■